

-- REMARKS --

The Applicant has carefully reviewed the statements the Examiner presented in the Final Rejection (mailed April 18, 2007) which rejected all of the claims of the application and has also carefully reviewed the cited references upon which the rejections are based. The Applicant has filed a Request for Continued Examination along with this Amendment F and respectfully requests reconsideration and re-examination of the claims of the application in view of the Applicant's amendments and responses to the rejection of the claims presented herein.

Claims Rejections under 35USC §102(b):

Claims 1, 4, 6, 9, 14-16, 19, 26, 28, 29, 32, 35, 36, 39, 44-47, 50-54, and 56 are rejected by the Examiner under 35USC §102(b) as being anticipated by Roucka (US 2,556,043) hereafter known as Roucka. Claims 1, 19, 29, and 39 are the independent claims within this group.

The Examiner describes Roucka as exhibiting all of the elements independent Claims 1, 29 and 39. Claims 1, 29, and 39 have been amended to include the limitations of a pressure sensor electronically senses pressure levels within the pressure vessel and provides pressure data feedback to an electronic control unit. Support for this amendment is found in the Applicant's specification in paragraph 0012 describing fluid pressure sensor 130. Roucka does not teach of an electronic pressure sensor providing data feedback to an electronic control unit. Since elements of the amended claims are not taught by Roucka, the 102(b) rejections are improper. The Applicant respectfully submits that Claims 1, 29, and 39 are in condition for allowance as amended. Allowance is hereby requested.

The Examiner describes Roucka as exhibiting all of the elements Claim 19. Claim 19 has been amended to include the limitation of a user operable, electronic switch toggles between

normal and abnormal blood pressure amplitude cycles experienced in the pressure vessel. Roucka clearly teaches that pressure level adjustments within his system require adjustments of several cumbersome mechanical screw drives (elements 19, 21, 55 and 57) which are both structurally and functionally extremely different than a user operated, electronic switch as claimed in the Applicant's invention. Switching between normal and abnormal states with Roucka's invention would be unwieldy at best involving the adjustment of several mechanical components which results in a slow change of states (a continuous change of states) rather than an abrupt change between discreet states by switch toggling which is much preferred so the user can readily compare, through feel, the discreet change between normal and abnormal blood pressure levels. Only with the Applicant's invention within this Claim 19 can toggling back and forth between discreet normal and abnormal states be achieved. Support for this amendment is found in paragraphs 0012 and 0013 of the application where element 160 is described as being an electronic switch in one embodiment that is user operable to allow the user to compare forces within the pressure vessel due to both normal and abnormal blood pressure levels. A user operable, electronic switch is inherently able to be toggled between states. All elements of the amended claim are not taught by Roucka, so the 102(b) rejection is improper. The Applicant respectfully submits that Claim 19 is in condition for allowance as amended. Allowance is requested.

Claim 54 was canceled since the essence of this dependent claim was included in the amended Claim 19.

Claims 4, 6, 9, 14-16, 26, 28, 32, 35, 36, 44-47, 50-53, and 56 are all dependent claims depending on above traversed independent Claims 1, 19, 29 and 39. For at least the reasons that the dependent claims contain all of the limitations of the respective claims on which they depend and since the Applicant submits that the independent claims are in condition for

allowance, the Applicant further submits all of the dependent Claims 4, 6, 14-16, 19, 26, 28, 32, 35, 36, 44-47, 50-53, and 56 are also in condition for allowance. Allowance of same is hereby requested.

Claims Rejections under 35USC §103(a):

Claims 2, 3, 10, 20, 21, 23, 30, 31, 37, 38, 40, 41, and 57 are rejected by the Examiner under 35USC §103(a) as being unpatentable over Roucka in view of Futcher et al (5,722,413) hereafter known as Futcher. Claim 57 is the only independent claim of the group.

In rejecting Claim 57, the Examiner points to the lack of teaching by Roucka of an elastomeric bulb than can be held in a human hand but goes on to state that Futcher teaches of the use of an elastomeric bulb whereby internal pressure amplitudes within the bulb are sensed by human touch. The Applicant respectfully submits that Examiner has made an improper combination of references to support his prima facie obviousness argument under 35USC §103(a) to reject this claim. The Applicant submits that its is improper to simply pick and choose components from prior art references as a "tool box" to reconstruct the Applicant's invention using hindsight without considering those references as a whole including those parts which teach away from the combination or where modification of the references would render a reference unsatisfactory for their intended purposes. Further, the proposed modification of a reference to arrive at the Applicant's invention cannot change the principle of operation of the reference.

First, one of the limitations of Claims 57 recites "an element to generate the pressurized fluid outside of the bulb whereby pressure levels of the pressurized fluid are pneumatically conveyed to inside of the bulb". Futcher clearly teaches away from this principle. The Examiner states in his reasons for rejection in the Final Rejection that "patient manually

squeezes the bulb to create a pressure on the manometer, (Column 4, Lines 1-3)". Futchter teaches of only one bulb in his system which both generates the pressurized fluid and provides a tactile interface for the user to feel the resistance as the bulb is squeezed. Therefore since Futchter's teachings must be taken in their entirety, Futchter clearly teaches away from the Applicant's invention since the element to generate the pressurized fluid in the Applicant's invention is not the same as the tactile interface.

Second, a combination of Roucka and Futchter renders Futchter unsatisfactory for its intended purpose. Futchter clearly teaches that the purpose of his invention is to provide the user a feeling of cardiac exertion as the heart pumps. If the bulb of Futchter was attached to the rubber tube of Roucka as suggested by the Examiner in an attempt to arrive at the Applicant's invention, then the intended purpose of Futchter would be destroyed since the system of Roucka already has a pressure pulse generating system included which would interfere with the intended purpose of a user compressing the heart-shape bulb of Futchter to receive physical feedback regarding cardiac exertion.

Third, a combination of Roucka and Futchter renders Roucka unsatisfactory for its intended purpose. If the bulb of Futchter was attached to the rubber tube of Roucka as suggested by the examiner in an attempt to arrive at the Applicant's invention, then the intended purpose of Roucka would be destroyed since manual compression of the heart-shaped bulb of Futchter when connected to the system of Roucka would result in highly inaccurate simulation of a circulatory system since both pump driven pressure pulses (Roucka) and manually driven pressure pulses (Futchter) would both be present in the Roucka system simulating a human circulatory system having two simulated beating hearts beating at the same time and unlikely in temporal phase due to the nature of the sources of pulsation.

Finally, the fact that references can be combined or modified is not sufficient to establish a prima facie obviousness rejection unless the prior art also suggests the desirability of the combination (MPEP section 2143.01). In re Mills, 916 F.2d 608, 16 USPQ2d 1430 (Fed. Cir. 1990) and In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).

The Applicant respectfully submits for the arguments listed above that the 35USC §103(a) rejection is improper and hereby requests that the rejection be withdrawn and Claim 57 allowed.

Claims 2, 3, 10, 20, 21, 23, 30, 31, 37, 38, 40 and 41 are all dependent claims which depend on independent claims which have been amended and/or traversed within this amendment and are therefore in condition for allowance. Since these dependent claims have all of the limitations of the claims on which they depend, the Applicant submits, for at least this reason, that Claims 2, 3, 10, 20, 21, 23, 30, 31, 37, 38, 40, and 41 are in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

Claims 7, 8, 13, 25, 27 and 34 are rejected under 35USC §103(a) as being unpatentable over Roucka in view of Tuney et al (US 5,991,654). Claims 7, 8, 13, 25, 27 and 34 are all dependent claims which depend on independent claims which have been amended and/or traversed within this amendment and are therefore in condition for allowance. Since these dependent claims have all of the limitations of the independent claims on which they depend, the Applicant submits, for at least this reason, that Claims 7, 8, 13, 25, 27 and 34 are in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

Claims 22 and 33 are rejected under 35USC §103(a) as being unpatentable over Roucka in view of Baldwin (US 4,773,865). In rejecting Claims 22 and 33, the Examiner points to the lack of teaching by Roucka of a manually operated pump to generate pressurized fluid but goes on to state that Baldwin teaches of the use of bulb syringe for pumping fluid. The Applicant respectfully submits that Examiner has made an improper combination of references to support

his prima facie obvious argument under 35USC §103(a) to reject these claims. The Applicant submits that it is improper to simply pick and choose components from prior art references as a "tool box" to reconstruct the Applicant's invention using hindsight without considering those references as a whole including those parts which teach away from the combination or where modification of the references would render a reference unsatisfactory for its intended purpose. (In fact, almost any invention could be reconstructed in this manner by selecting specific prior art components without restriction). Further, the proposed modification of a reference to arrive at the Applicant's invention cannot change the principle of operation of the reference.

First, Roucka teaches of a closed loop system wherein the simulated blood recirculates and the total fluid volume is fixed in order to properly simulate a complete human circulatory system by passing blood through simulated lungs, main vessels, peripheral circulation, etc. and returning blood back to the various chambers of the heart, each chamber having its own mechanical adjustments for simulating various physiological and pathological factors. If the complex mechanical pumps were replaced by a simple bulb syringe taught by Baldwin as the Examiner suggests, then Roucka would not operate in its intended purpose. Also, the principle of operation of Roucka would be altered since the various heart abnormalities could not be simulated nor could the filling of the simulated heart chambers be simulated with the Examiner's suggested combination of Roucka and Baldwin.

Second, the fact that references can be combined or modified is not sufficient to establish a prima facie obviousness rejection unless the prior art also suggests the desirability of the combination (MPEP section 2143.01). In re Mills, 916 F.2d 608, 16 USPQ2d 1430 (Fed. Cir. 1990) and In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).

The Applicant respectfully submits for the arguments listed above that the 35USC §103(a) rejection is improper and hereby requests that the rejection be withdrawn and Claims 22 and 33 be allowed.

Also Claims 22 and 33 are both dependent claims which depend on independent claims which have been amended and/or traversed within this amendment and are therefore in condition for allowance. Since these dependent claims have all of the limitations on the independent claims on which they depend, the Applicant submits, for at least this reason, that Claims 22 and 33 are in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

Claim 42 is rejected under 35USC §103(a) as being unpatentable over Baldwin, in view of Roucka. The Examiner points to Baldwin's teaching of a first elastomeric bulb to pressurize fluid and to a second elastomeric bulb (a simulated femoral artery 52' in a simulated leg) which is pneumatically connected to the first bulb through a bi-directional flow connection such that the pressure in the second bulb is controlled by the amount of compression in the first bulb; the second bulb providing a tactile interface to the human subject where the human subject physically senses the fluid pressure magnitudes internal to the second bulb by gripping the with at least one hand. The Examiner then combines the teaching of Roucka to add a visual indicator to the teaching of Baldwin in an attempt to arrive at the Applicant's invention. The Applicant respectfully submits that the tube to simulate a femoral artery 52' in Baldwin is very clearly buried deeply within the simulated leg 36 (see Fig. 6 of Baldwin) whereby it would not be physically possible for a human hand to grip this element as is a limitation in Claim 42 of the Applicant's invention. Also, just as important, the simulated femoral artery 52' of Baldwin is not a second elastomeric bulb. See Applicant's specification paragraph 0016 where its taught that one function of an elastomeric bulb is to provide significant force amplification within the

pressure vessel compared to the force exerted on the walls of relatively small diameter conduits. The Applicant teaches an advantage of an elastomeric bulb over a relatively small diameter tube (52' in Baldwin) which the Examiner improperly considered as an equivalent of an elastomeric bulb in rejecting Claim 42. Since every limitation of Claim 42 is not taught by a combination of Baldwin and Roucka, the Applicant submits that the 35USC §103(a) rejection is improper and should be withdrawn. Additionally, the fact that references can be combined or modified is not sufficient to establish a prima facie obvious rejection unless the prior art also suggests the desirability of the combination (MPEP section 2143.01). In re Mills, 916 F.2d 608, 16 USPQ2d 1430 (Fed. Cir. 1990) and In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. The Applicant requests that the rejections be withdrawn and Claim 42 allowed.

Claims 11, 43, and 55 are rejected under 35USC §103(a) as being unpatentable over Roucka in view of Baldwin, in view of claims 1, 19, and 42 and in further view of Frazier (US 6,669,624), hereafter known as Frazier. Claims 11, 43, and 55 are all dependent claims which depend on independent claims which have been amended and/or traversed within this amendment and are therefore in condition for allowance. The Applicant submits that the Examiner has misunderstood the purpose of the incompressible, non-liquid member inside of the elastomeric hollow bulb serving as a tactile interface. This member is not included to aid in inflation and deflation as the Examiner suggests, but rather to provide a substrate for the user of the device to press the bulb walls against to maintain a consistent feel and to reduce the tendency for the user to randomly squeeze the bulb during the blood pressure simulation (see paragraph 0013). As such, the combined teachings of Roucka, Baldwin, and Frazier to arrive at the Applicant's invention would render Baldwin's invention unsatisfactory for its intended purpose since a user cannot pump a bulb to simulate a femoral artery pulse while they are compressing the walls of the bulb against an internal, non-compressible member thereby

maintaining a consistent feel and reducing the tendency for the user to randomly squeeze the bulb during the blood pressure simulation. Pumping the bulb would not provide a consistent feel. The combination of the references would also render Frazier unsatisfactory for its intended use since the bulb in Frazier is not intended to be compressed by a human hand and, in fact, is not possible to do so in its intended use inside the vascular system of a human. Also, since these dependent claims have all of the limitations on the independent claims on which they depend, the Applicant submits, for at least this reason, that Claims 11, 43, and 55 are in condition for allowance and requests that the rejections be withdrawn and the claims allowed.

The Applicant has traversed all of the independent claims active in the application and believes they are now in condition for allowance. Allowance is hereby requested. Further, the Applicant believes all dependent Claims are in condition for allowance for at least the reason that they contain all limitations of their respective independent claims. Allowance is hereby requested.

The Applicant notes that the Roucka reference does not appear on Notice of References Cited page of the Final Rejection.

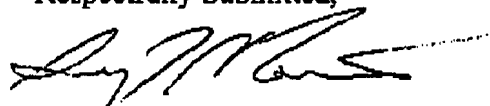
Summary

The Applicant has filed a Request for Continued Examination along with this Amendment F.

The Applicant has addressed each of the Examiner's rejections of the claims either by amending claims or by traversing the rejections. No new matter has been added by Applicant in the amendments herein. The Applicant believes that all of the claims are now in condition for allowance and respectfully requests that the rejections be withdrawn and the claims allowed.

If the Examiner believes that a telephone conversation would be useful to advance the prosecution of this application, the Applicant may be reached at (304)290-9942 at any time.

Respectfully Submitted,



Gary J. Morris, Ph.D.
Reg. No. 56,689
2026 Glenmark Avenue
Morgantown, WV 26505
(304)290-9942